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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/323,854	06/02/1999	CHERK SHING TAM	79997/124	9723

7590 07/29/2002
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EXAMINER

ROMEO, DAVID S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 07/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/323,854

Applicant(s)

TAM, CHERK SHING

Examiner

David S Romeo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-53 is/are pending in the application.
- 4a) Of the above claim(s) 24-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49-51 and 53 is/are rejected.
- 7) ☒ Claim(s) 52 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The amendment filed May 20, 2002 (Paper No. 16) has been entered. Claims 24-53 are pending.

5 Applicant's election with traverse of group XXI, claims 1-23 to the extent that they are drawn to a polypeptide comprising the amino acid sequence of SEQ ID NO: 46, in Paper No. 16 is acknowledged. The traversal is on the ground(s) that there is no undue search burden in searching SEQ ID NOs: 44-46 and Applicant's request that claims 49-53, submitted in place of elected group XXI, be examined together. Pursuant to Applicant's request, claims 49-53 will be
10 examined together.

The requirement is still deemed proper and is therefore made FINAL.

Claims 24-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

15 Applicant timely traversed the restriction (election) requirement in Paper No. 16.

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

20 An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). It is acknowledged that the first sentence of the specification contains a reference to 08/763,458, but this reference is not

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specific in that it does not indicate, or it is ambiguous, whether the present application is a division, continuation, or continuation-in-part of 08/763,458. When a nonprovisional application (other than a CPA) is entitled under 35 U.S.C. 120 to an earlier U.S. effective filing date, a statement such as "This is a division (continuation, continuation-in-part) of Application No. ---, filed ---" should appear as the first sentence of the description or in an application data sheet. Status of nonprovisional parent applications (whether it is patented or abandoned) should also be included. If a parent application has become a patent, the expression, "Patent No. __" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "abandoned" should follow the filing date of the parent application. Also the continuing data in the first sentence of the application does not agree with the continuing data in the oath or declaration.

Appropriate correction is required.

15 The application is not fully in compliance with the sequence rules, 37 C.F.R. § 1.821-1.825. Specifically, the specification fails to recite the appropriate sequence identifiers at each place where a sequence is discussed. See the Abstract. This is not meant to be an exhaustive list of places where the specification fails to comply with the sequence rules. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors.

20 Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. The application cannot issue until it is in compliance. Nucleic acid sequences with 10 or more nucleotides, at least 4 of which are specifically defined, must comply

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with the sequence rules. Amino acid sequences with 4 or more residues, at least 4 of which are specifically defined, must comply with the sequence rules. Sequence identifiers can also be used to discuss and/or claim parts or fragments of a properly presented sequence. For example, language such as "residues 14 to 243 of SEQ ID NO:23" is permissible and the fragment need
5 not be separately presented in the "Sequence Listing."

Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

10 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which
15 applicant regards as the invention.

Claim 49 is indefinite because it is unclear if position number 9 is to be substituted with a nonpolar or uncharged polar amino acid or if a nonpolar or uncharged polar amino acid at position number nine can be substituted with any amino acid. The metes and bounds are not clearly set forth.

Double Patenting

20

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).
25

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

5 Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 49-51, 53 are rejected under the judicially created doctrine of obviousness-type
10 double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6117839 (c17) in view of Houghten (a17) and Chait (b17). The claims of the present application are directed to a polypeptide comprising the amino acid sequence of SEQ ID NO: 46 wherein position number 9 can be substituted with a nonpolar or uncharged polar amino acid. The claims of the patent are directed to a polypeptide comprising the amino acid sequence of amino acids 5-14 of SEQ ID
15 NO: 1 or a substituted variant thereof. The present applications SEQ ID NO: 46 is related to the patent's SEQ ID NO: 1 as follows:

```

1 XTQEHTAESX 10
  | | | | |
5 RTNEHTADCK 14.

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20

The present application at page 46, lines 7-9, defines a nonpolar amino acid as G, A, P, V, or I, and at page 46, lines 9-11, defines an uncharged polar amino acid as S, T, M, C, N, or Q. The patent teaches that interchange among non-polar aliphatic neutral amino acids, glycine, alanine, proline, valine and isoleucine, would be possible. Likewise, substitutions
25 among the polar aliphatic neutral amino acids, serine, threonine, methionine, cysteine, asparagine and glutamine could possibly be made. The examiner uses the present application's and the patent's specifications as definitions of the terms nonpolar or uncharged polar amino acid. Q at position 3 and S at position 9 of the present application's SEQ ID NO: 46

and N at position 7 and C at position 13 of the patent's SEQ ID NO: 1 are all uncharged polar amino acids and/or are encompassed by the types of substitutions envisioned by the present application and the patent.

The claims of the present application are directed to a polypeptide comprising the amino acid sequence of SEQ ID NO: 44. The present applications SEQ ID NO: 44 is related to the patent's SEQ ID NO: 1 as follows:

```
1 XTQEHTAEAX 10
  | | | | |
5 RTNEHTADCK 14.
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Claim 1 of the patent recites "a substituted variant ... in which cysteine has been substituted by alanine". Thus, the present application and the patent are claiming overlapping subject matter, which subject matter is encompassed by the nature and type of substitutions envisioned in both the claims of the present application and the claims of the patent.

The Xaa at position 1 and the Xaa at position 10 of the present application's SEQ ID NOs: 44 and 46 are N-acetyl arginine and lysinamide, respectively, whereas the amino acid at positions 5 and 14 of the patent's SEQ ID NO: 1 are arginine and lysine, respectively. It would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to replace the lysine at position 14 with lysinamide with a reasonable expectation of success. One of ordinary skill in the art would be motivated to make this modification because it is known in the art to synthesize peptides that include a N-terminal acetyl group and a C-terminal amide group (Houghten (a17), claim 5), wherein the N-terminal acetyl group is N-acetyl arginine (Houghten (a17), column 63, information for SEQ ID NO: 5), and L-lysine has at least two desirable properties as a terminating reagent for use in peptide ladder generation. First,

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L-lysineamide is highly water soluble. This allows its use at high molar concentration. Secondly, L-lysineamide contains a basic moiety and, therefore, may enhance peptide ladder detection when the means to be used for analyzing the peptide is MALDI mass spectrometry because basic groups can aid in ionization. See Chait (b17), paragraph bridging columns 5-6.

5

Conclusion

Claim 52 is rejected as being dependent upon a rejected base claim.

10

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

15

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEFORE FINAL (703) 872-9306

AFTER FINAL (703) 872-9307

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20

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

25



DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

30

DSR
JULY 28, 2002